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**Transfer of  
Contraceptive Production Technology to  
Developing Countries**

by Michael J. Free,  
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## Preface

This *PIACT Paper, Transfer of Contraceptive Production Technology to Developing Countries*, addresses an area of increasing importance to national family planning programs. As these programs expand and introduce new contraceptive technology, it is essential that a continuing source of contraceptive supplies be available. Where it is feasible and economical, the establishment of local contraceptive production capability can help countries attain the goal of contraceptive self-sufficiency. PIACT now has several years of experience in assessing the feasibility of and in implementing local contraceptive production projects. Currently, PIACT is working with colleagues in the People's Republic of China, Indonesia, Mexico and Brazil to develop local production facilities which will produce contraceptive products to meet local demand. *PIACT Paper Nine* is a reprint from the proceedings of the International Symposium on Research on the Regulation of Human Fertility, held in Stockholm, Sweden, February 1983. The paper summarizes PIACT's experience and addresses some of the important issues related to local production.

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## Transfer of contraceptive production technology to developing countries

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No consensus exists on the value of local production as a supply option for contraceptives. The views of donor agencies, service organizations, multinational firms, and developing countries are frequently divergent on this issue. At present, 20 developing countries have contraceptive use rates above the level required for full-scale production of orals, IUDs or condoms. Fourteen of these countries already have some production capacity or have conducted feasibility or pre-investment studies in preparation for technology transfer. In most cases, current local production capacity is not sufficient to meet local, public sector demand. Often, the local products are competing with donor-supplied imported contraceptives which are distributed free of charge or at a subsidized price. The problems of technology transfer to developing countries for contraceptive production are common to the establishment of any industrial technology requiring high standards of quality, rigorous good manufacturing practices, and precision equipment. These problems can be overcome, but the process requires more time than is usual for the developed world, and project costs can escalate rapidly. Costs of the finished product may not be lower than those in the developed world in spite of lower costs for land, buildings, labour, raw materials or other inputs. However, savings in foreign exchange currencies can be expected when compared with purchase of imported products. Careful planning on the part of developing countries and donor agencies can ensure the optimum outcome for local production decisions. The decisions will not always be made solely on the basis of technical and economic feasibility.

Transfer of family planning technologies, in the broad sense, incorporates the development, adaptation, introduction, and supply of the fertility control methods for use in developing countries. Most of these activities are discussed in detail by other authors in this symposium. In this paper we focus upon the issue of supply and, in particular, the option of manufacturing contraceptives in developing countries, for local or regional distribution.

The practical implication of the long development time scales for new contraceptive methods, bearing in mind the additional several years required to introduce the technologies effectively into diverse family planning programmes, is that the technologies of greatest significance for control of population growth are already in use, or at least in clinical trials (Berelson 1978; Fathalla 1978; Mauldin 1979). Some new delivery systems may involve combinations of pharmaceutical and plastic processes which will be method-specific. Excluding these and the primary synthesis or extraction of active pharmaceutical agents, most of the emerging methods involve production or secondary processing technologies now in common use. Therefore, production of condoms, oral contraceptives and long-lasting copper IUDs has been used as the basis for discussion throughout this paper.

Transfer of contraceptive production technology to developing countries is not only a technical and micro-economic issue. It also has global implications, involves international and national issues of a political and macro-economic nature and, among other perspectives, must be viewed in the broad context of development and industrialization.

The discussion that follows considers local production or final processing of contraceptives in developing countries as one set of options for increasing national self-support of family planning during the 1980's. The objectives of this document are to bring together the several viewpoints on this topic, to summarize the scattered information on current local production activities, and to discuss the problems and special requirements for technology transfer in developing countries.

### Advantages and disadvantages of contraceptive production in the developing world

An understanding of the different points of view on contraceptive supply issues helps to explain the different restraints, limitations and policies of international donor agencies, multinational industries and local authorities. A discussion of these frequently divergent views may contribute to the development of plans and strategies for long-term contraceptive supply that are acceptable to all parties.

The following are summaries of some of the views on local production that have been expressed by donors, manufacturers and representatives of developing country governments (Mahoney 1982; Free et al. 1982). Although these views may be significant in influencing the policy of major agencies, institutions or local

authorities, they are by no means meant to represent the views of all international or local bodies involved in contraceptive supply.

### *Arguments against local production of contraceptives*

1. Local production would increase the cost of contraceptive commodities to the remainder of the public sector.

Most contraceptives used in national family planning programmes are produced by a relatively small number of private firms. By producing a narrow range of uniformly packaged products in large quantities for centralized public sector procurement, and avoiding the usual marketing and distribution costs associated with private sector sales, these manufacturers have been able to produce consistently high quality products at reasonable and stable prices. These low prices clearly depend upon continued high demand and large centralized procurement funds. Decreased demand and a diversion of funds for local production could endanger these low prices.

2. Donor supply of contraceptives to qualified host countries can be expected to continue as long as needed.

The issue of unchecked population growth is regarded as being of sufficient global concern that significant long-term donor supply of contraceptives can be expected even though short funding cycles dictate that contracts and guarantees must usually be short-term. Even if shortfalls between donated commodities and local demand have to be met by international procurement with local funds, the total cost for donated plus locally funded goods is likely to be considerably lower than the cost to manufacture locally. Continued large-scale and long-term international support for family planning in the developing world appears to diminish the benefits of local production.

3. Technological and quality requirements of contraceptive production are not readily achieved in developing country settings.

Technologies for production of contraceptives are generally environmentally sensitive and technology-intensive. There is a risk associated with these technologies under the extreme climatic and low technology environment of the developing world. The strict quality requirements for contraceptive production demand an inflexible adherence to specifications and standards which may not be readily achieved under these conditions. Quality control difficulties also include inadequate national inspection facilities and politicized management systems.

4. The cost of locally produced products must be compared with that for centrally procured goods.

Using bilateral or multilateral agencies as central procurement agents, local authorities can take advantage of low prices resulting from large-scale procurement from multinational or other large manufacturers. The drain on international

currency reserves resulting from local procurement of contraceptives is not likely to amount to more than a few per cent of total foreign imports into a developing country. With this option, high quality products could be guaranteed without the risks attendant upon local production.

5. Publicly operated contraceptive or drug industries do not have a good track record.

Publicly operated industries (in both developed and developing countries) may not have the incentives or the accountability to achieve an efficient level of production or rigorous control system sufficient to maintain acceptable standards of quality. Private industry or joint ventures may be better able to achieve these goals in countries with private sector economies. However, while the private sector might be attracted by the market for locally manufactured substitutes for imports, private investment may be discouraged by difficulties in assessing the market, perceived political instability, concern with 'single customer' public sector markets, lack of patent or trademark protection, cumbersome price controls or counter-productive import regulations and tariffs on raw materials and equipment.

6. Local contraceptive production is not the most effective use of development capital.

Industrial projects resulting in reduced foreign currency expenditures alone do not fully realize the benefit of the capital investment. Utilization of raw materials and other local resources to make exportable products, as distinct from importing raw materials to make domestic products, should be the key criteria for public development projects in the developing world.

7. Alternative supply options may be more acceptable to some international organizations.

From the perspective of some international donors or multinational industry, local production is not seen as the best strategy for long-term supply of contraceptives in the developing world. These organizations would prefer an alternative strategy, involving continued donor contribution of contraceptive commodities, making efficient use of donor funds in a way that is accountable and acceptable to the governments and their constituencies in the donor countries. The donor agencies would provide low interest loans combined with a centralized procurement service for countries not qualifying for commodity grants, or where shortfalls existed between demand and donated supplies. Local resources could then effectively be directed toward improving logistics, storage and distribution systems, motivating new acceptors and training new service providers. Donor assistance or support for local production projects would be looked at carefully on a case-by-case basis only in the context of a broad development strategy.

### *Arguments in favour of local production of contraceptives*

From some points of view a number of benefits arise from local production of contraceptives, providing contraceptive use is sufficient to justify a reasonable scale of production technology.

1. Contraceptives may be viewed as strategic commodities, essential for national survival.

The strategic view of a contraceptive commodity, as being essential for national survival, transcends all of the usual least cost and industrial investment criteria. Securing and controlling the means of production for these 'strategic' commodities becomes imperative even though this supply alternative may cost more or have other deficiencies. This view may become more prevalent as nationalist tendencies increase and the awareness of the negative aspect of population growth on development becomes more widely held.

2. Local production ensures continuity of supply and facilitates long-term planning for national population strategy.

Planning national population strategy five or ten years into the future is impeded by uncertainty of donor supplies beyond the current fiscal period. At the same time, planning for contingency supplies in the event of shortfalls or termination of donor supplies has often been neglected, perhaps because of a viewpoint that such planning for self-reliance will send signals to donor agencies that will hasten the end to donor contribution. In the instances where planning does occur in the new climate of uncertainty about sustained donor contributions, it frequently includes an exploration of the local production option, recognizing that a lead time of two to five years is required to develop these capabilities.

3. Significant manufacturing inputs are available in many developing countries.

Many developing countries can provide energy (hydroelectric, natural gas), raw materials (latex, steroid sources, packing materials such as paper and cellulose, clean water), highly trainable, and low cost manpower, cheap land and construction materials. Even if some raw materials and machinery have to be imported, the value added through local inputs can effect substantial savings in foreign currency expenditures over international procurement.

4. Excess pharmaceutical production capacity exists in some developing countries.

In some developing countries, excess capacity in either public or private sector (pharmaceutical) manufacturing may already exist for a variety of economic reasons. By encouraging the utilization of this capacity for production of contraceptives the productivity of already invested capital can be significantly increased.

5. Local production allows for effective donor assistance while reducing donor dependency.

Donor assistance, in the form of raw materials and/or local procurement of

finished products, in contrast to supply of commodities, provides a more secure basis for the development of long-term self-support in contraceptive supplies. In the event of a sudden downturn in donor assistance, the developing country with production capability is better able to meet its needs with the minimum drain upon its foreign currency reserves.

6. Local production develops skills and infrastructure.

Local production promotes the development of indigenous skills, creation of jobs, utilization of local resources and possible development of external trade.

7. Local packaging of contraceptives facilitates development of culturally appropriate packages.

The packaging of contraceptive products is an important motivational and instructional factor in family planning programmes because packages are a key way of communicating message about a product and its correct use. Local production or even local testing and packaging of imported bulk products facilitates development of packaging and instructional inserts that are culturally appropriate. It also allows packaging in sizes appropriate for transport and rural health services use.

8. By remaining constant over a long period of time, locally produced goods and packages can retain brand familiarity.

Locally produced goods can appear identical over a long period of time, thereby avoiding the confusion and uncertainty among providers and users that can arise when donated products are changed because of competitive bidding practices or multiple donors.

9. Local production can engender national pride.

The sustaining and motivating qualities of pride, self-esteem and national identity may become dominant factors in national decision making.

This divergence of views on the local production option for long-term supply of contraceptives may have some beneficial effects, making for a restrained and cautious approach to decision-making and promoting more careful study of the risks and benefits. All points of view can be tempered by careful case-by-case studies of technological and financial capability on the part of the developing country. However, even a favourable feasibility analysis may not be enough in some cases to surmount the 'real world' difficulties of political instability, ineffective or politicized management systems, loss of donor or service agency assistance, or other intangibles. Many of these can only be minimized by clear policies and strategies on the part of local authorities, donors and assistance agencies, together with honest attempts to explain and resolve the conflicts of national interest that may arise among the concerned parties.

## Candidate countries for local production of contraceptives in the developing world

### *Limits of scale*

Full-scale production of contraceptives (not necessarily including raw material production) can only be carried out efficiently at production volumes above a minimum scale of operation. Minimum production capacities are dictated by the capacity of plant and machinery and by the need for relatively fixed cost management, environmental control, quality assurance and other operations which become prohibitively expensive at smaller scales of operation. Present estimates of minimum annual capacity for the principal contraceptives are approximately 70 million condoms\*, 15 million oral contraceptive cycles\*\*, and one million copper IUDs per year. Coincidentally, these minimum scales of operation each serve approximately one million users per year.

These estimates assume that no other products are manufactured in the same facilities. Facilities manufacturing a variety of products may efficiently produce or package smaller quantities of contraceptives, since the non-contraceptive products will absorb some of the fixed or minimum costs (see section Cost considerations for discussion of cost components).

Based upon the estimated minimum capacities, only a few countries can be identified that have present or near future contraceptive use rates sufficient to warrant consideration of full-scale local production as an option for supply of contraceptive commodities (Population Reports 1981; Nortman & Hofstatter 1980; Man'louk 1982). These are listed in Table 1. Some of these countries already have some local production of one or all of these commodities (see next section).

If groups of small nations should decide to produce on a regional basis, local production may become a wider issue. In the absence of regional co-operation, an objective that the majority of countries may realistically aspire to is establishing a packing and/or testing operation utilizing imported bulk condoms or IUDs, or mixed pharmaceutical formulating, tableting and packaging operations in which oral contraceptives or injectables constitute a part of a wider range of drug products serving the health needs of the population.

In the relatively few countries with volume requirements above the minimum for efficient production, and for the many more for which testing and packaging operations could be scaled to meet need, many factors other than production volume impinge upon the feasibility or practicability of local involvement in contraceptive production. Careful feasibility studies are required to examine these factors for each specific country.

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\* Technologies for efficient production of 20 to 30 million condoms/year are available, but have not been tested under developing country conditions.

\*\* Secondary pharmaceutical processing only. Quantities as low as one million/year are being produced in multiproduct tableting plants. However, the need for special environmental and worker safety controls makes this scale of operation less feasible unless the plant is already equipped to handle steroids.

## Current status of contraceptive production in developing countries

Contraceptive factories exist in at least fourteen of the most populated developing countries (Table 2). Most have been developed during the past ten years. Plans or feasibility studies for additional products or expanded production are under way in several of these countries as well as in some others that do not have existing production facilities (Tcheknavorian-Asenbauer & Noe 1975; Mahoney 1982).

Only five countries with sufficient use rates for full-scale production (Table 1) are entirely without some local manufacturing capability, or development activity (IUD: Thailand and the Republic of Korea; Condoms: Pakistan, Philippines, Vietnam). However, most of the local producers in other countries are meeting only a fraction of the local needs for contraceptive products. In most cases, they do not supply the public sector. They operate, to a varying extent, in competition with donor agency imports of goods which are distributed free, or at a heavily subsidized cost, to the user.

When considering local production as a supply option, the primary question is not whether or how to transfer technology to developing countries, but rather, how best to support, improve and expand existing capabilities to serve local needs.

*Table 1.*  
Countries with contraceptive use rates sufficient to meet minimum production capacity.

Current rates sufficient		
Condoms	Oral Contraceptives	IUDs
Bangladesh	Bangladesh*	Egypt*
Brazil*	Brazil*	India*
India*	Egypt*	Indonesia
Indonesia	India*	Republic of Korea
Republic of Korea*	Indonesia*	Mexico*
Pakistan	Republic of Korea*	Pakistan*
People's Republic of China*	Mexico*	People's Republic of China*
Philippines	Pakistan*	Thailand
	People's Republic of China*	
Vietnam	Thailand*	
Near future rates sufficient		
Mexico*	Colombia*	Brazil
Turkey	Nigeria	Vietnam
	Philippines*	

\* Currently producing, but in most cases, not in sufficient quantity to meet local public sector demand. See Table 2.

*Table 2.*  
Current status of contraceptive production.

Country	Method			
	Injectable steroids	OCs	IUDs	Condoms
Argentina		P(M)		P(M)
Bangladesh		P(M), uc		uc
Brazil		P(M)	uc	P(L)
Colombia		P(M)		
Egypt		G	G	
India		G, P(M)	G	G, P(M)
Indonesia		G, P(M)	uc	uc
Mexico	P(M)(L)	P(M)	P(L)	P(L)
Pakistan		P(M)	P(L)	uc
People's Republic of China	G	G	G	G
Republic of Korea				P(L)
Thailand	P(L)	P(M)		uc
Philippines		P(L)		uc
Turkey		P(M)		uc
Vietnam				uc
Chile		P(M)		
Bolivia		P(M)		
Venezuela		P(M)		
Equador		P(M)		

G = Government controlled. P = Private ownership. P(L): Local: owned by business people of the developing country. Some minor amounts of foreign capital may be involved. P(M): Multinational: either export their products to developing country factories for local packaging, or carry out partial or complete manufacture in developing countries using, in both instances, subsidiary or joint venture companies. uc = under consideration.

### Cost considerations in local production

#### *Project costs*

The current cost (1982) of setting up complete contraceptive production capabilities at the minimum economic scale in a developing country is likely to be in the range of US \$ 5 to 8 million for condom production, US \$ 4 to 6 million for oral contraceptive formulation and tableting, and US \$ 2 to 3 million for sterilized, individually packaged, long-life copper IUD production. These investments do not include costs of financing or of tariffs or duties for import of machinery and equipment (Free et al. 1982). In each case, 20% to 40% of these costs will be in local currencies, while the remainder will require international exchange currency. Local

costs will be much more variable from country to country than the international currency component, which is required especially for the purchase of capital equipment and components in international markets.

All of the initial investments can be substantially reduced or spread over several years by importing semifinished products or components and limiting local activities to final operations such as assembly, packaging, testing, and sterilization. For example, the investment cost for testing and packaging 70 to 90 million condoms per year, including a six-month supply of bulk condoms and other materials, is approximately US \$ 2.5 to 3 million. However, as less local value is added to the product, the less 'affordable' international currency component of production cost increases.

*Production cost:*

The cost of production in the developing world setting will vary considerably from country to country, depending upon, among other things, 1) the cost of manpower, which for unskilled or semiskilled workers, for example, can range from US \$ 30 to

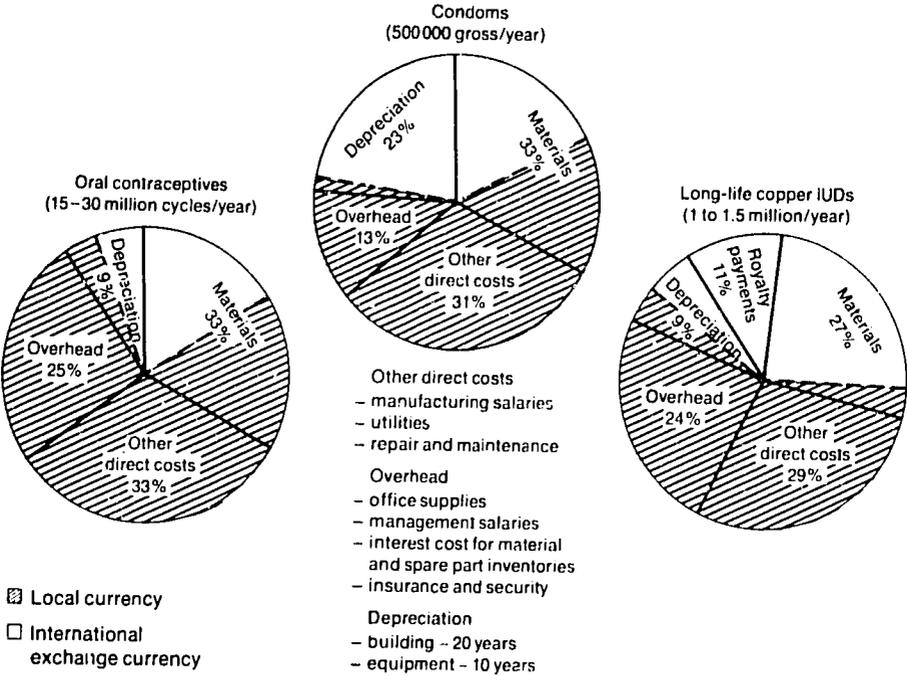


Fig. 1.

Contribution of major cost components to the cost of contraception production in developing countries.

US \$ 200 per month depending upon the country and economic sector; 2) tariffs, duties and taxes on imported materials, as well as unofficial levies, which can double the cost of these inputs; and 3) the availability of local energy (natural gas, oil, hydroelectric). Substitution of local for imported raw materials may not have a large impact upon cost of production but can reduce international exchange expenditures.

The contribution of major cost components to the overall production cost of different contraceptives is shown in Fig. 1. The condom costs assume the use of imported latex and chemicals. All cases assume that some local packaging materials are available. IUD costs assume imported plastic blends and copper components, on-site molding and EtO sterilization, as well as a royalty fee, repatriated to a foreign patent holder. In the case of condoms, substitution of local for imported latex and primary chemicals can substantially reduce the foreign currency expenditures, but not the total production costs. For the other two technologies, substantial reduction of foreign currency expenditures is more difficult unless the country has a source of steroids or an advanced petrochemical industry. The overall costs can be reduced by greater economies of scale or by diversification of products (e.g. surgical gloves and tubing production in the condom factory; general pharmaceutical production in addition to oral contraceptives; molded plastic medical goods such as syringes and cannulae produced in the IUD facility).

The conclusion from several cost studies in developing countries (Kabalikat 1980; PIACT 1980, 1981a, 1982a; Free et al. 1982) is that the overall production cost of locally produced contraceptives may be similar or even marginally higher than international prices of similar goods from large multinational companies. Furthermore, these production costs do not include the cost of research and development, interest on capital loans, or of marketing. However, substantial (40–80%) savings in international exchange currency can result from local production, especially if suitable raw materials are available locally.

From the donors' perspective, reducing foreign exchange requirements is equivalent to reducing the total cost of the commodities, since the same number of dollars can be spread further. Support for local production does, therefore, offer an approach to at least one as yet unresolved problem. The number of couples in reproductive age groups in developing countries is projected by UNFPA to grow by two-thirds by the year 2000 (UNFPA 1982). The required commodities can only be provided by one of three means: 1) at least doubling of donor support available for the purchase of commodities; 2) shifting the entire responsibility for production or purchase to the developing country; 3) some type of partnership in which donor funds are reserved for those costs that are most difficult for Third World governments to meet.

To oppose support for local production, where it is feasible, is to assume that donor funds for the continued purchase of large quantities of contraceptives will not only continue, but will increase substantially in the immediate future. If such an

assumption is uncertain or unfounded the question of support for local production becomes not 'whether' but rather 'when' and 'how best' to assure a successful outcome.

## Transferring contraceptive production technologies to developing countries

### *Assessing feasibility*

#### *Purpose and nature of feasibility studies*

Local production of contraceptives implies a decision to invest millions of dollars in an industrial project and to base national plans for supply of vital commodities upon the success of that venture. Obviously, such decisions are approached cautiously, with careful study of the financial, economic and technical feasibility of the project, as well as its impact on present supply systems and the existence of alternative options.

The goal of pre-investment studies (UNIDO 1978) is 1) to provide investment opportunity information sufficient to allow potential investors (private sector entrepreneurs, foreign firms seeking joint ventures, or multilateral and bilateral donors) to become involved as early as possible in the evaluation of the project; 2) to reach a firm 'go/no go' investment decision point at the earliest time and with minimum expenditure. The approach that is taken to achieve this goal generally involves a series of studies which increase gradually in scope and depth until a decision can be made to abandon the project or to proceed with investment and implementation. A variety of decision pathways exist (Fig. 2) depending upon the degree of promise evident at each stage of the investigation.

#### *Special problems and considerations in assessing feasibility of industrial projects in developing nations*

A large number of factors must be taken into consideration in assessing the feasibility of local production in developing nations. Information from standard detailed industrial economic and technical feasibility studies must play a central role in the analysis, but, in addition, a number of other considerations must be taken into account. Many of these special considerations apply generally to the developing world, and some are specific to particular countries, regions or socioeconomic systems.

*Impact on donor-supported programmes.* One consideration is the short- and long-term impact of local production upon donor assistance. A related concern is the impact on distribution schemes such as social marketing programmes, which usually rely upon donated goods. An example of the type of legitimate concern that could arise

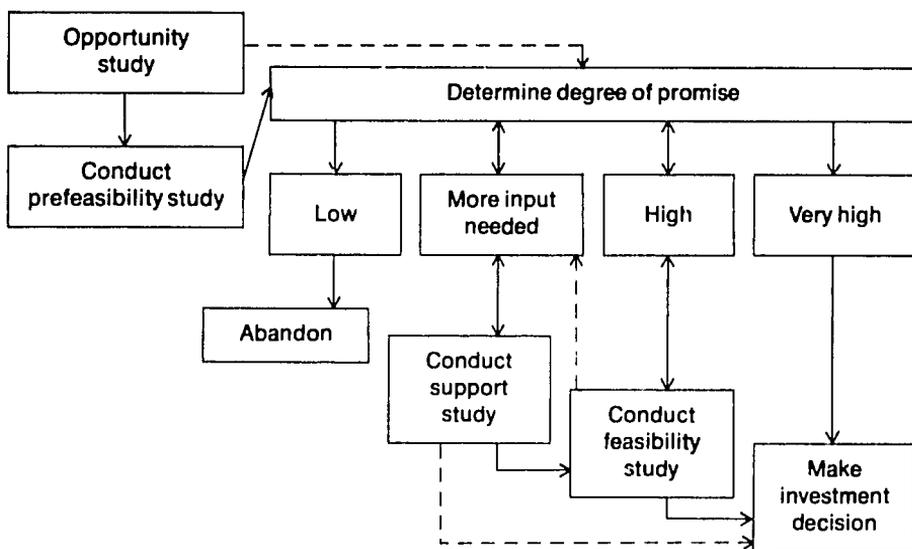


Fig. 2.  
Decision pathways for investment in industrial projects.

among this donor and service community is the quality of the goods that might be produced, particularly in the first few years, by inexperienced local operators using imported technology. It is unlikely that a commercial retail sales or social marketing programme, distributing a substantial percentage of a nation's contraceptives, using tried, tested, and accepted products, will be eager to commit to the unknown products of a new factory without substantial assurances of sustained quality. Furthermore, these programmes may currently utilize commodities supplied without charge by a bilateral agency, which under normal circumstances can only supply goods purchased in its home country. It is evident that phasing-in of local products, even at prices below world market, has a major impact upon the existing supply systems. It cannot be done effectively without an integrated approach toward the entire supply and distribution operation that enlists the full co-operation of the local government, local industries and the donor and service agencies that give their support to the developing country.

*Accuracy of needs assessment.* An accurate assessment of current and future need is paramount to good planning for commodity supply. This is especially true when the information is to be used as a basis for an investment decision regarding local production. Plans for future contraceptive requirements are often based on insubstantial or inaccurate data and can be unrealistic with respect to total quantities of contraceptives required to meet future needs as well as the product mix.

Projections of future contraceptive needs require an understanding of the characteristics of the various methods including estimates of continuation and discontinuation rates.

Although the number of couples at risk in a country may indicate a substantial future demand for contraceptives, the distribution systems and motivational activities required to reach and activate those couples are usually severely limited. Reaching the whole population with information and education, and making contraceptives universally available, require efforts and resources many times that required to buy or make the contraceptives. If plans for expansion of these promotional and logistical systems are unrealistic, estimates of future contraceptive utilization can be severely distorted. When assessing feasibility of local production, special studies of present and future demand for contraceptive products may be required to sharpen the estimates of required production rates.

*Social/technical considerations.* Because of special social or technical situations in developing countries, unusual or unexpected costs must be considered and taken into account for feasibility assessment. Examples of these are:

- the losses in productivity resulting from interruptions or reductions in the power supply or other utility services, and the downtime while waiting for critical spare parts, which can be offset only by large capital expenditures for emergency supply capabilities;
- rapid turnover of trained personnel due to intense competition between industries or government departments for scarce technically trained manpower, and the large disparity between public and private wage scales;
- losses due to migration of skilled workers from developing countries to developed ones. UNCTAD estimates that between 1961 and 1972, 'developing countries gave the USA, Canada and England close to US \$ 44 billion in the form of 231 000 skilled migrants (World Development Letter 1982).
- losses due to mis-shipping and mishandling of intricate equipment and supplies in an infrastructure with difficult communications and transportation systems, and fragile record-keeping systems.
- quality control problems resulting from a breakdown in the intricate organizational arrangements, the consistent attention to details of seemingly gratuitous or redundant operations, and the high level of personal responsibility required at all levels of the work force. Additional and costly quality indemnities must be built into the manufacturing scheme, including outside audit, for good manufacturing practices and routine quality control checks by independent and qualified agencies, or licensors.

*Political uncertainties.* Political instability obviously discourages outside investments in long-term local projects, although reversal of national family planning or population policies resulting from changes in government are unusual. Perhaps a more insidious political uncertainty arises from 'politicized' management structures

where power is not related to skill or experience and managers are not directly accountable for the quality and cost of their products.

Other difficulties for technology transfer arise in nations with centralized economies, where private sector joint ventures are limited or non-existent and the public sector must carry out the entire development programme. In these economies, the centers of expertise and technical know-how which lie in the private sector of most major donor nations cannot be linked directly and continuously to the project, but rather must be contracted on a turnkey or piecemeal basis without the motivating and cost-saving benefit of vested interest. Technology transfer can be successfully carried out under these conditions if a sufficiently high priority is accorded to the project so that adequate local resources can be mobilized and a high level of management accountability maintained.

### *Options for implementation*

#### *Role of the private sector*

Both the private sector and the public sector are almost always involved, at some point, in the process of technology transfer although the degree of participation by each sector may vary enormously. At the one extreme, the private sector of an industrial nation may simply sell, directly, or through an independent intermediate agency, machinery for a project developed in the public sector of a developing nation. At the other extreme, a private sector company from an industrial nation may participate with a private firm from a developing country in a continuing joint venture where the only public sector involvement is in the facilitation of the project through special duty or tax concessions, guaranteed purchase of product or simply permission to operate. In between these two extremes there exists a wide variety of arrangements, for example, joint ventures between private and public sector; enlisting the services of an independent executing agency to manage the project; turnkey contracts for factories to be run by the public sector with or without follow-on assistance arrangements; management contracts by which private firms run public factories; expansion of existing private sector capabilities to meet public sector needs. These options are not always available or applicable in every case and need to be examined for each specific product and within each national setting.

#### *Final processing of bulk products*

Another subset of options involves the several levels of production activity ranging from final packaging of imported bulk, tested products on the one hand, to complete processing, testing and packaging on the other. At the latter extreme, local production of raw materials may also be included.

Latex, processing chemicals, fillers, and some packaging materials are examples of component raw materials which may be available in some developing countries, but which do not, by themselves, make full-scale production of mechanical or

chemical contraceptives feasible or practical. Steroids are also produced in a few of the larger developing countries or in countries with abundant supplies of the source materials, but require a large capital investment and a substantial market for the product. Most countries have formulating and tableting capabilities for secondary production of pharmaceuticals. However, adapting these to produce hormonal contraceptives requires special measures for worker safety and environmental controls, which can only be justified at a larger scale of production.

The development of local industries for testing and/or packaging of bulk products may be one way in which all of the disparate interests – donors, manufacturers and developing country governments – may be aligned in favour of local participation in the production of needed commodities. The developed world manufacturers, in many cases, have, by reason of scale and efficiency, reduced primary production costs to very low levels. However, costs of packaging and testing, are often inherently more dependent upon labour and material costs. Because of this, packaging and testing may lend themselves, much more than total processing, to local enterprise in some developing countries. Testing and packaging can be economical at much lower levels of output. The large manufacturers in the developed world would find sufficient economic incentive to sell bulk products to the bilateral donor agencies at favourable prices. The developing country would continue to benefit from donated commodities in the form of bulk contraceptives for local testing and packaging. In the case of USAID assistance, the requirement of providing only USFDA-approved contraceptive supplies could be fulfilled in this manner. At the same time the developing country would be a partner rather than a passive recipient in the supply of its own family planning commodities. Furthermore, packaging and instructional/motivational materials could be more effectively adapted to local cultural conditions, and new skills and organizational structures would accrue. The packaging and testing facility would be an effective technological proving ground for future expanded enterprises, yielding tangible proof of the ability or inability of a system to handle the larger task of full-scale production. However, this coalition of advantages still depends upon a constant and continued source of bulk products at a price that reflects the true cost of production.

### *Specific product considerations*

*Condom production.* (Free 1981) Condom production industries have evolved somewhat independently in Japan, England and the United States. They draw their basic technology from the general experience of the latex dipping industries, but the fine details of production are proprietary industrial practices. Because of these factors, condom production capabilities cannot reasonably or economically be acquired piecemeal by accumulating pieces of equipment from various manufacturers and attempting to develop a process by trial and error. Rather, the buyer must select a production *system* and put his needs in the hands of a single condom equipment supplier. Since condom production is a very specialized form of latex dipping, the

project risks are diminished if the equipment supplier has also developed and refined its equipment within the condom industry. Furthermore, since the condom dipping process is sensitive to the environment and raw materials, the project risks are diminished further if the equipment supplier has had experience in setting up and adapting condom technology in tropical and/or developing country conditions. However, even within a selected production system, some options are available. Licenses are not generally granted for condom production. Joint ventures or subsidiaries of large companies are more common. Turnkey technology transfers have been carried out in the past, but do not have a good record of success.

*Production of IUDs and other plastic devices.* (Free 1982a) Injection molding of plastic parts for IUDs or MR kits requires high precision tools and good molding practices, but does not require specialized equipment or techniques exclusive of those used by the plastic molding industry. The addition of copper wire windings, copper collars, or active agents to an inert plastic IUD requires a variety of specialized equipment which must be custom designed and built or obtained from an IUD manufacturer. All of the plastic industries producing medical devices have moved toward more stringent good manufacturing practices in the past few years, prompted by the new USFDA medical device (Free 1982b) regulations.

IUD production operations can range from assembly and packaging of purchased components to full-scale molding operations. In existing large-scale IUD production operations, it is common to have contractors perform some or all of the following procedures: blend the plastic material for the IUD frame; manufacture the copper components; make molds; perform injection molding and extrusion; sterilize.

Most IUDs are made under license from the developers of particular designs. IUD technology is unique among contraceptive technologies in that it is presently available from both the private and public sector, making a wide variety of technology transfer arrangements possible.

*Steroid contraceptive production.* Except in the People's Republic of China, most steroid contraceptive manufacturers in the developing world are linked in some way to large multinational corporations. A few developing countries (e.g., People's Republic of China, India, Brazil) have developed primary pharmaceutical plants to produce steroids. Generally, however, the raw materials are imported, and the local factory operation involves secondary pharmaceutical procedures for formulating, tableting or vial filling, and packaging. These factories are often multi-product pharmaceutical manufacturing plants, providing a number of drug formulations for local use.

Adding oral contraceptive production to an existing multi-product facility creates a problem of cross-contamination between hormonal steroids and other products. This problem requires construction of a small oral contraceptive formulation, tableting and packing facility, with separate dust collection, air handling, and safety

systems, within the larger facility. Equipment in the pharmaceutical industry is constantly evolving and being upgraded, so that a wide variety of equipment is available. Good Manufacturing Practices and worker safety are critical in this industry and require costly investments in plant and environmental control, as well as in quality assurance.

*Manufacture of probable future contraceptives.* Although many of the probable new family planning products of the next ten years will require secondary pharmaceutical processing similar to present tablets and injectables, some of the methods (implants, vaginal rings, micro-capsules) will require combinations of plastic and pharmaceutical methods. Although some of these combination production technologies have been developed over the past ten years by a few industries and laboratories pioneering in slow-release forms of medication, no broad, international methodology exists. The manufacturing processes for these products will be product-specific and under the control, initially, of a few developers and their licensees. Diffusion of these production technologies is, therefore, likely to be slow and the cost high, except where the technology is owned by the non-commercial sector (Mahoney 1982).

*Quality control.* Quality control refers to all those activities undertaken by a production facility to ensure precision, reliability and conformance to material and product specifications. Quality control requires a high degree of skill, appropriate (and often sophisticated) equipment; strict adherence to standards, specifications, and Good Manufacturing Practices; and very close official supervision. Pharmaceutical production, formulation, and quality control require a supply of trained manpower, and key personnel need to have academic and industrial training in the relevant areas. There is need, then, for a developing country considering local production to have the basic educational infrastructure for science and technology. There is also a real need for standards and for action to implement national codes and enforcement policies.

### Strategies for effective decision making

The following strategies are offered as suggestions for further discussion and amplification. In some cases the strategies are already being carried out to some degree; others represent statements which are obvious in principle, although they may need more conscious and concerted effort in practice.

#### *Strategies for donors*

Major donors could ease the transition from donor-dependency to self-support for developing country family planning programmes by supporting the following strategies.

*Clear statement of policy.* A clearly stated donor policy regarding phase-in of local responsibility for commodity supply would provide a basis for long-term planning. This policy should remove the uncertainty surrounding future donor supplies, extend for as long as possible the period over which commodity supplies can be guaranteed, and provide clear indications of how, and under what conditions, donor agencies are prepared to assist in the development of self-support supply systems (international procurement with local funds and/or local production).

*Case-by-case analysis.* Given the complex array of circumstances that determines the success or failure of local production in developing countries, generalizations about capability or feasibility have little meaning, except with respect to the volume of goods required by the country's programmes and its ability to pay for imported materials. Inside of these broad limits, each case must be separately studied to determine the technical, economic and financial feasibility, present and future product mix, impact upon present supply systems and options for implementation of local production projects. Where feasibility studies are called for, donors and assistance agencies can make available to local authorities the technique and management resources of the developed world to work with developing world counterparts in order to provide the clearest possible picture of the costs, advantages and risks associated with local production in each specific setting.

A systematic and detailed survey of the experiences of local manufacturers in developing countries could provide useful models for assessing local production possibilities. No such systematic study has been attempted, and only scattered anecdotal information is available.

*Co-operation with the private sector.* Private industry has a proven track record for effective and efficient transfer of technology and production of high quality goods at low cost. If mechanisms could be found to encourage, promote or support business ventures leading to contraceptive production in developing countries, the chances of a successful outcome would be increased.

Some possibility exists for a partnership in which the large technology-based health industries of the world can earn access to Third World markets for their more profitable ethical products by lending their research capabilities in pursuit of appropriate Third World-directed technologies, including contraceptive products.

*Optimizing local production projects.* Donor agencies can encourage and support effective decision making and project execution by providing funds for technical assistance, procurement, training and other project costs. These funds should be made contingent upon incorporation, at appropriate stages of the project, plans, designs, equipment and protocols necessary for Good Manufacturing Practices and quality assurance of the final products. Participation of an experienced, independent executing agency can also be useful and cost-effective, particularly when donor funds are involved in a major industrial project.

Donor assistance can provide local authorities with guidelines and assistance in *designing appropriate regulatory policies* and in assuring the quality of goods procured from local companies or from regional or international sources.

*Promoting regional co-operation.* The pooled markets or public sector demand of several countries in a region can provide a basis for cost saving central procurement of local production. Furthermore, manpower, material and financial resources can be pooled to reduce risk and distribute the cost. Unfortunately, very few countries have been disposed toward regional co-operation. The need for multi-level agreements as well as high levels of mutual trust and confidence has constrained the development of regional arrangements for commodity supply. Nevertheless, the potential advantages of regional co-operation are sufficient to warrant continued encouragement.

*Improving logistics.* The bottleneck of most developing country family planning and population programmes is still the limited outreach and/or inadequate supply systems. As developing countries take greater responsibility for their own contraceptive supply needs, they are likely to be more motivated to improve other aspects of their supply systems. At this stage, increased donor assistance for improving supply and distribution systems could be highly cost-effective in reducing waste, improving the quality of goods reaching the user and increasing the impact of national family planning programmes.

*Facilitating discussion of future supply options.* Issues discussed throughout this paper should be brought to the attention of developing country authorities, donors, and assistance and service agencies, and discussed by means of workshops, conferences, published case studies, and regional or local meetings. Donor field offices could take the initiative in organizing local discussion of these issues to clarify long-term contraceptive supply options.

### *Strategies for developing countries*

As developing country authorities develop plans for self-support in family planning commodities, they can take action to pave the way for a smooth transition and maintain a variety of options for self-support. Some possible strategies are listed below.

*Working for firm donor commitments.* Developing countries can work with donor and assistance agencies to formulate clear-cut plans for phase-in of local procurement or local production.

These plans may involve loans or grants for feasibility studies, development of production capabilities or procurement of commodities. They may also include central procurement services, quality assurance services or continued assistance with raw materials or intermediate products to support production or packaging

operations. Studies could be performed to verify the benefits of lower cost packaging options that might be appropriate to the local setting.

*Lowering import barriers.* In many cases counterproductive tariffs, duties or taxes exist on family planning-related materials or equipment in developing countries even where family planning programmes are given high national priority. Careful review of these levies and elimination of those which directly or indirectly tax family planning programmes would help to encourage trade in family planning commodities and increase the impact of investments in this area.

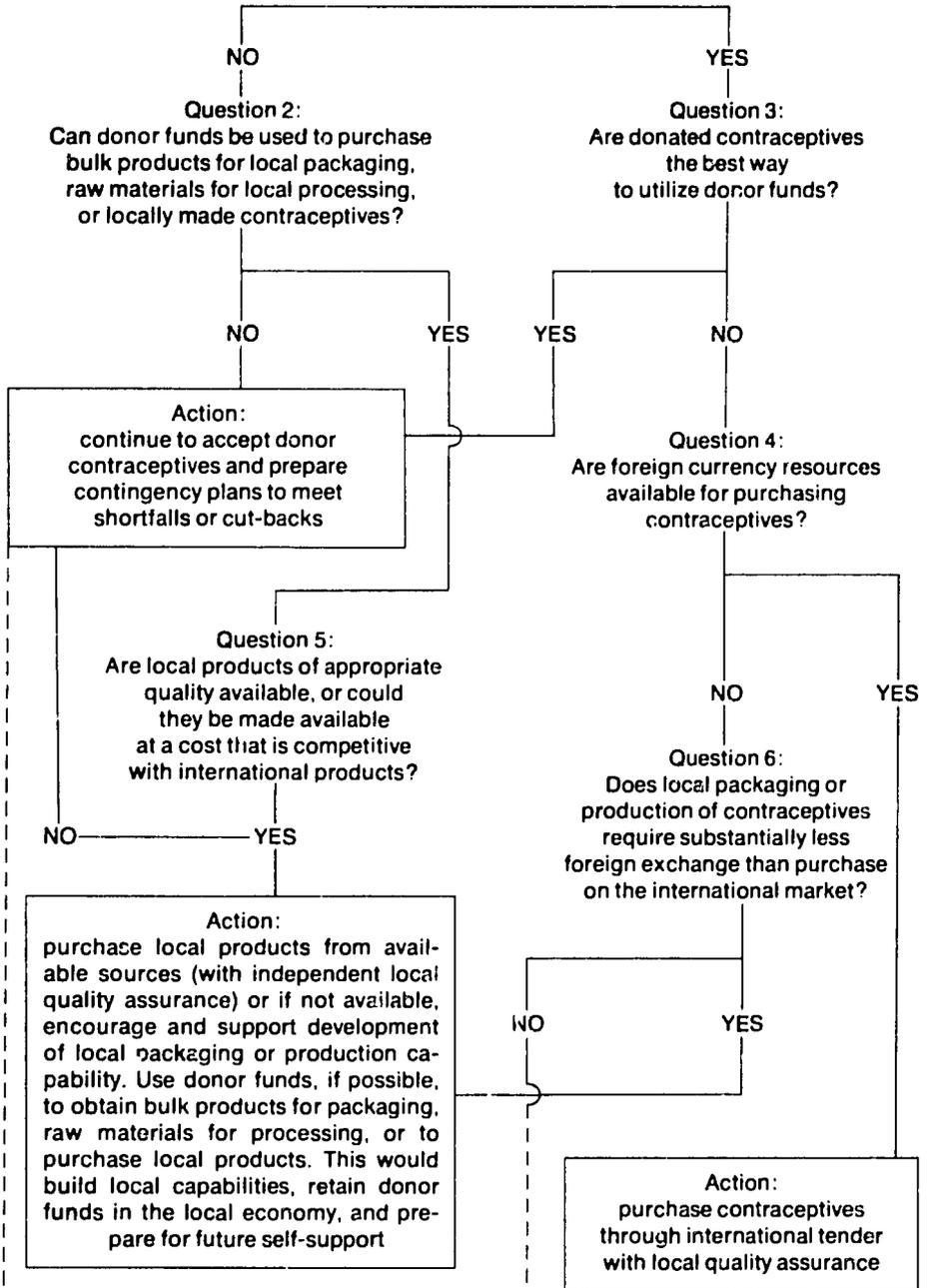
*Improving the investment climate.* Countries interested in involving the international private sector in the local production of contraceptives should ensure that their laws provide adequate protection of patents and trademarks. Without this protection, the transfer of technology through joint ventures or licenses is less likely to be attractive to investors or patent holders. Providing special tax holidays and other incentives such as adequate repatriation of dividends to foreign investors may also be useful. Developing country authorities can also conduct their own promotional campaign in pursuit of private sector contraceptive production technology by collecting and making available resource data relevant to an investment decision. These data may include cost and availability of manpower, skills, raw materials and land, as well as accurate assessment of market or public sector demand for the products, details of distribution systems and other information. If raw materials such as latex or steroid derivatives are available in a country, plans might be implemented as early as possible to evaluate, upgrade and exploit these resources so that material of appropriate quality can be available for use in future production operations.

*Establishing national drug and device regulatory authorities.* Maintenance of quality is a top priority for any local system of contraceptive supply. If developing countries seeking out their own least cost supplies of contraceptives, elect to procure by worldwide tender or turn to local production, a national system of quality regulation will be essential.

These regulatory authorities should have access to testing laboratories with a range of chemical and physical testing capabilities sufficient to meet USP, BP or other major compendial and ISO standards. A system of receipt checks for government purchases, as well as regular factory and shelf checks for local goods, should be instituted. A Good Manufacturing Practices code should be adopted and enforced by regular inspection of factories and materials.

*Increasing the efficiency of programmes.* The efficiency of family planning programmes can be improved by upgrading the logistical systems, by encouraging the use of more cost effective long-life methods such as sterilization, IUD or steroid implants, and by improving continuation rates. All of these can reduce, in the long run, the cost of contraceptive supply and will affect the choice of supply system.

**Question 1:**  
 Can donor funds presently used to purchase contraceptives be shifted to other needs?



*Fig. 3.*  
 Critical decisions on contraceptive supply options.

### *Critical decision paths for choosing supply options*

If local production is found to be technically and economically feasible, there remains the question of whether local production makes sense in the light of other supply options. Some critical decision paths that lead to a resolution of this question are suggested in Fig. 3. This decision path assumes that the country is already receiving contraceptive supplies at no cost from a donor agency. Referring to Fig. 3, it is recommended that:

- a) questions 1, 2, and 3 be resolved in discussions with donor agencies;
- b) question 4 should be resolved by the local governments' planning and budgeting authorities, if and as necessary;
- c) in order to fully resolve question 5, a dialogue should be initiated with local manufacturers currently producing, or having sufficient technical sophistication to produce, contraceptives, as well as with foreign manufacturers;
- d) in order to resolve question 6, feasibility studies will be required.

At an early stage in planning for supply options, discussions are required with leaders of all major distribution programmes (Community-Based Distribution; Social Marketing; Clinic Distribution, etc.) in the private and public sectors, in conjunction with donor agencies, in order to detail special programme needs, desired product characteristics, and problems associated with alternative sources of contraceptive supply, so that changes in contraceptive supply can be planned and carried out without jeopardizing existing programmes or destroying the good will necessary for successful co-operation.

### Epilogue

This paper has considered local production of contraceptives from several viewpoints: Perceptions of contraceptive supply and production issues, factors in the decision making process, and current production status have been reviewed; a number of strategies have been suggested. Hopefully, the continuing debate on self-support for family planning in the developing world will stimulate organizations and authorities to gather more information and to clarify the many outstanding issues.

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